Complete Summary

GUIDELINE TITLE

Electrophysiologic testing and use of devices in heart failure: HFSA 2006 comprehensive heart failure practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Heart Failure Society of America. Electrophysiologic testing and the use of devices in heart failure. J Card Fail 2006 Feb; 12(1): e70-5. [47 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Heart Failure Society of America. Heart Failure Society of America (HFSA) practice guidelines. HFSA guidelines for management of patients with heart failure caused by left ventricular systolic dysfunction--pharmacological approaches. J Card Fail 1999 Dec; 5(4):357-82.

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

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SCOPE

DISEASE/CONDITION(S)

Heart failure

GUIDELINE CATEGORY

Evaluation Treatment

CLINICAL SPECIALTY

Cardiology Internal Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for the electrophysiologic testing and the use of devices in heart failure

TARGET POPULATION

Patients with heart failure

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Implantable cardioverter defibrillator (ICD)
- 2. Biventricular pacing therapy

Note: The routine use of dual (atrioventricular [AV]) chamber pacemakers for heart failure in the absence of symptomatic bradycardia or high-grade AV block is not recommended.

MAJOR OUTCOMES CONSIDERED

Morbidity and mortality associated with heart failure

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Databases searched included Medline and Cochrane. In addition, the guideline developers polled experts in specific areas for data.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level A: Randomized, Controlled, Clinical Trials May be assigned based on results of a single trial

Level B: Cohort and Case-Control Studies Post hoc, subgroup analysis, and meta-analysis Prospective observational studies or registries

Level C: Expert Opinion Observational studies – epidemiologic findings Safety reporting from large-scale use in practice

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Heart Failure Society of America (HFSA) Guideline Committee sought resolution of difficult cases through consensus building. Written documents were essential to this process, because they provided the opportunity for feedback from all members of the group. On occasion, consensus of Committee opinion was sufficient to override positive or negative results of almost any form or prior evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

"Is recommended": Part of routine care Exceptions to therapy should be minimized.

"Should be considered": Majority of patients should receive the intervention. Some discretion in application to individual patients should be allowed.

"May be considered": Individualization of therapy is indicated

"Is not recommended": Therapeutic intervention should not be used

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The process of moving from ideas of recommendations to a final document includes many stages of evaluation and approval. Every section, once written, had a lead reviewer and 2 additional reviewers. After a rewrite, each section was assigned to another review team, which lead to a version reviewed by the Committee as a whole and then the Heart Failure Society of America (HFSA) Executive Council, representing 1 more level of expertise and experience. Out of this process emerged the final document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The strength of evidence (A, B, C) and strength of recommendations are defined at the end of the "Major Recommendations" field.

General Considerations

 It is recommended that the decision to undertake electrophysiologic intervention be made in light of functional status and prognosis based on severity of underlying heart failure (HF) and comorbid conditions. If left ventricular (LV) dysfunction is a reason for recommending electrophysiologic intervention, LV function should be reassessed, ideally after 3-6 months of optimal medical therapy. (Strength of Evidence = C)

Electrophysiologic (EP) Testing and Evaluation of Syncope

- Immediate evaluation is recommended in patients with HF who present with syncope. In the absence of a clear identifiable noncardiac cause, patients should be referred for EP evaluation. (Strength of Evidence = C)
- Routine EP testing is not recommended in patients with LV systolic dysfunction who have asymptomatic nonsustained ventricular tachycardia (VT) in the absence of prior infarction. (Strength of Evidence = B)

Prophylactic Implantable Cardioverter Defibrillator (ICD) Placement

- In patients with or without concomitant coronary artery disease (including a prior myocardial infarction [MI] >1 month ago):
 - Prophylactic ICD placement should be considered (left ventricular ejection fraction [LVEF] ≤ 30%) and may be considered (LVEF 31%-35%) for those with mild to moderate HF symptoms (New York Heart Association [NYHA] II-III). (Strength of Evidence = A)

See the recommendation under "General considerations" above for additional criteria.

 Concomitant implantable cardioverter defibrillator placement should be considered in New York Heart Association class III or IV patients undergoing implantation of a biventricular pacing device according to the criteria in the recommendations under "Biventricular resynchronization pacing" below (Strength of Evidence = B)

See the recommendation under "General considerations" above for additional criteria.

- ICD placement is not recommended in chronic, severe refractory HF when there is no reasonable expectation for improvement. (Strength of Evidence = C)
- ICD implantation is recommended for survivors of cardiac arrest from ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia without evidence of acute myocardial infarction (MI) or if the event occurs more than 48 hours after the onset of infarction in the absence of a recurrent ischemic event. (Strength of Evidence = A)

Biventricular Resynchronization Pacing

- Biventricular pacing therapy should be considered for patients with sinus rhythm, a widened QRS interval (≥120 ms) and severe LV systolic dysfunction (left ventricular ejection fraction ≤35% with LV dilatation >5.5 cm) who have persistent, moderate to severe HF (New York Heart Association III) despite optimal medical therapy. (Strength of Evidence = A)
- Selected ambulatory New York Heart Association IV patients may be considered for biventricular pacing therapy. (Strength of Evidence = B)
- Biventricular pacing therapy is not recommended in patients who are asymptomatic or have mild HF symptoms. (Strength of Evidence = C)

Dual Chamber Pacemakers

• The routine use of dual (atrioventricular [AV]) chamber pacemakers for HF in the absence of symptomatic bradycardia or high-grade atrioventricular block is not recommended. (Strength of Evidence = A)

Definitions:

Strength of Evidence

Level A: Randomized, Controlled, Clinical Trials May be assigned based on results of a single trial

Level B: Cohort and Case-Control Studies
Post hoc, subgroup analysis, and meta-analysis
Prospective observational studies or registries

Level C: Expert Opinion Observational studies – epidemiologic findings Safety reporting from large-scale use in practice

Strength of Recommendations

"Is recommended": Part of routine care Exceptions to therapy should be minimized.

"Should be considered": Majority of patients should receive the intervention. Some discretion in application to individual patients should be allowed.

"May be considered": Individualization of therapy is indicated

"Is not recommended": Therapeutic intervention should not be used

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations").

The recommendations are supported by randomized controlled clinical trials, cohort and case-control studies, and expert opinion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate electrophysiologic testing and use of devices in heart failure

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

It must be recognized that the evidence supporting recommendations is based largely on population responses that may not always apply to individuals within the population. Therefore, data may support overall benefit of 1 treatment over another but cannot exclude that some individuals within the population may respond better to the other treatment. Thus guidelines can best serve as

evidence-based recommendations for management, not as mandates for management in every patient. Furthermore, it must be recognized that trial data on which recommendations are based have often been carried out with background therapy not comparable to therapy in current use. Therefore, physician decisions regarding the management of individual patients may not always precisely match the recommendations. A knowledgeable physician who integrates the guidelines with pharmacologic and physiologic insight and knowledge of the individual being treated should provide the best patient management.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Pocket Guide/Reference Cards Slide Presentation

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Heart Failure Society of America. Electrophysiologic testing and the use of devices in heart failure. J Card Fail 2006 Feb; 12(1): e70-5. [47 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 (revised 2006 Feb)

GUI DELI NE DEVELOPER(S)

Heart Failure Society of America, Inc - Disease Specific Society

SOURCE(S) OF FUNDING

Heart Failure Society of America, Inc

GUIDELINE COMMITTEE

Comprehensive Heart Failure Practice Guideline Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members and reviewers from the Executive Council received no direct financial support from the Heart Failure Society of America (HFSA) or any other source for the development of the guideline. Administrative support was provided by the Heart Failure Society of America staff, and the writing of the document was performed on a volunteer basis by the Committee. Financial relationships that might represent conflicts of interest were collected for all members of the Guideline Committee and of the Executive Council, who were asked to disclose potential conflicts and recuse themselves from discussions when necessary. Current relationships are shown in Table 1.5 of the "Development and Implementation" companion document (see the "Availability of Companion Documents" field).

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management of patients with heart failure caused by left ventricular systolic dysfunction--pharmacological approaches. J Card Fail 1999 Dec; 5(4): 357-82.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Heart Failure Society of America, Inc. Web</u> site.

Print copies: Available from the Heart Failure Society of America, Inc., Court International - Suite 240 S, 2550 University Avenue West, Saint Paul, Minnesota 55114; Phone: (651) 642-1633

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Heart Failure Society of America. Executive summary: HFSA 2006 comprehensive heart failure practice guideline. J Card Fail 2006 Feb; 12(1):10-38.
- Heart Failure Society of America. Development and implementation of a comprehensive heart failure practice guideline. J Card Fail 2006 Feb; 12(1):e3-9.
- Heart Failure Society of America. Conceptualization and working definition of heart failure. J Card Fail 2006 Feb; 12(1):e10-11.

Electronic copies: Available from the <u>Heart Failure Society of America, Inc. Web site</u>.

• PowerPoint slides. HFSA 2006 comprehensive heart failure guideline.

Electronic copies: Available from the <u>Heart Failure Society of America, Inc. Web site</u>.

The following is also available:

• Heart Failure Society of America. Pocket guide. HFSA 2006 comprehensive heart failure practice guideline.

Electronic copies: Not available at this time.

Print copies: Available from the Heart Failure Society of America, Inc., Court International - Suite 240 South, 2550 University Avenue West, Saint Paul, Minnesota 55114; Phone: (651) 642-1633

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 31, 2006. The information was verified by the guideline developer on August 10, 2006.

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